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Start of union reviews

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Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Mysimba	naltrexone / bupropion	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Mysimba. This was prompted by remaining concerns regarding the potential long-term cardiovascular risk (affecting the heart and blood circulation) with Mysimba and its impact on the benefit-risk balance of the medicine.

Table 2. Start of harmonisation procedure

Name	Active substance	Type of procedure	Scope
Havrix	hepatitis A virus (inactivated, adsorbed)	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Havrix and associated names. The review was triggered by GlaxoSmithKline Biologicals, due to the need of harmonisation of the Summary of Product Characteristics across Member States, plus Norway and Iceland, where the product is approved.